DATE 30 Sep 03

USAMMDA INFORMATION PAPER

PRODUCT: LEISHMANIA SKIN TEST

DESCRIPTION: The *Leishmania* Skin Test will be a U.S. Food and Drug Administration (FDA) approved skin test for the screening of U.S. Service members who may have been exposed to *Leishmania* species (parasites) after deployment to leishmaniasis endemic areas of Africa/Southwest Asia. The skin test for *Leishmania* is made according to the same general principles as the skin test for tuberculosis. The *Leishmania* test is performed by injecting a small amount of purified *Leishmania* proteins under the skin and then measuring any local skin reaction 48-72 hours later. A small bump of 5mm or greater is a positive indication the individual has been exposed to the *Leishmania* parasite. A pre-planned product improvement program has begun to expand the diagnostic capabilities to detect exposure to *Leishmania* species from Latin America countries. The disease leishmaniasis occurs in 88 countries around the world and is caused by protozoan parasites transmitted to humans from the bite of an infected sandfly. More than a million new cases of human leishmaniasis are reported annually in the world. Currently some 12 million people throughout the world suffer from leishmaniasis. The cutaneous form of the disease can sometimes cause highly mutilating lesions on one's skin/face, wherever an infected sandfly bites. In the city of Kabul, Afghanistan, an estimated 270,000 cases of cutaneous leishmaniasis occurred in 1996 among the less than 2 million inhabitants of the city. Visceral leishmaniasis is the most severe form and attacks the spleen, liver and lymph nodes. Left untreated, this form of the disease is usually fatal within several years.

PROGRAM RELEVANCE to the ARMY: This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities" by providing a capability to easily screen large number of U.S. Forces for exposure to the *Leishmania* parasites. The *Leishmania* Skin Test will improve sustainability in tropical and temperate regions of the world. In addition, this product supports Future Operational Capability MD 97-003 (Patient Treatment and Area Support) and MD 97-006 (Hospitalization).

ISSUES/ ACTIONS:

- Responsibility for future clinical studies, clinical data analysis, and regulatory database management needs to be shifted to the contract manufacturer. The contract was modified in 4QFY03.
- The entire development program must be re-baselined to address the time required to license a multivalent skin test. This new acquisition program schedule will be presented at the next milestone meeting.

BPL #: 344
DA PROJECT/TASK: Infectious Diseases
PE/PROJ 643807.808PD
PE/PROJ 654807.849PD
PE/PROJ 643807.837PD
PE/PROJ 654807.834PD
MAMP RANK: 17/36
ARMY ORD: Antileishmanial Medical Systems
(CARDS #14008), 29 Jan 1997

SCHEDULE:

MS I	4QFY97
MS B	1QFY03
MS FRP	4QFY05

For additional information, contact: Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051